DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2003E-0405 and 2003E-0452]

Determination of Regulatory Review Period for Purposes of Patent Extension; NEUTERSOL

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for NEUTERSOL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of two applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of two patents which claim that animal drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT:

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Office of Regulatory Policy (HFD-013),

Center for Drug Evaluation and Research,

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SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product.

Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product NEUTERSOL (zinc gluconate). NEUTERSOL is indicated for chemical sterilization in 3- to 10-month-old male puppies. Subsequent to this approval, the Patent and Trademark Office received two patent term restoration applications for NEUTERSOL (U.S. Patent Nos. 5,070,808 and 4,937,234) from Technology Transfer, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated November 18, 2003, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of NEUTERSOL represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office

requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for NEUTERSOL is 4,222 days. Of this time, 4,188 days occurred during the testing phase of the regulatory review period, and 34 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) involving this animal drug product became effective: August 27, 1991. The applicant claims November 14, 1991, as the date the investigational new animal drug application (INAD) became effective. The applicant relied on this date based on a letter sent to the applicant by the document room on November 14, 1991 which provided the INAD number to the applicant. However, this letter was not intended to serve as an official acknowledgment of the INAD filing. FDA records indicate that the filing of a notice of claimed investigational exemption was August 27, 1991, which is considered to be the effective date for the INAD.

2. The date the application was initially submitted with respect to the animal drug product under section 512(b) of the act: February 12, 2003. The applicant claims February 10,

2003, as the date the new animal drug application (NADA) for NEUTERSOL (NADA 141-217) was initially submitted. However, FDA records reveal that NADA 141-217 was submitted on February 12, 2003.

3. The date the application was approved: March 17, 2003. FDA has verified the applicant's claim that NADA 141-217 was approved on March 17, 2003.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments and ask for a redetermination by [insert date 60 days after date of publication in the FEDERAL REGISTER]. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by [insert date 180 days after date of publication in the FEDERAL REGISTER].

To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted except that individuals may submit one copy. Comments are to be identified with

the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: _____.

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Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research